REMARKS

The pending Office Action addresses claims 1-9 and 13-27, rejecting claims 1-9 and 13-27.

Amendments to the Claims

Applicant amends independent claim 1 to specify that the sensor element is positioned within the ventricular cavity and that the system controller device communicates remotely via telemetry with the implantable shunt system. Support for this amendment can be found throughout the specification, for example, at page 9, lines 11-14 and page 10, lines 9-12. Applicant also amends independent claim 17 to specify that the system controller device communicates remotely via telemetry with the implantable shunt system. Support for this amendment can be found throughout the specification, for example, at page 10, lines 9-12. No new matter is added.

Rejection Pursuant to 35 U.S.C. §102

The Examiner rejects claims 1-8 and 13-16 pursuant to 35 U.S.C. §102(e) as being anticipated by US 2003/0004495 A1 of Saul ("Saul 495"). Applicant respectfully disagrees.

Independent claim 1, as amended, recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient. The method includes providing an implantable shunt system having a sensor element positioned within a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the shunt system.

Saul 495 fails to teach or even suggest a method of regulating cerebrospinal fluid flow including such features. Saul 495 discloses a method for removing cerebral spinal fluid (CSF) from a CSF space of a patient at constant volumetric rates. First, Saul 495 does not teach positioning a sensor element within the ventricular cavity, as required by amended claim 1. Instead, Saul 495 uses a sensing device to detect the volume of flow *exiting* the CSF space over a period of time. (Saul 495 page 5, lines 22-28). Second, Saul 495 fails to disclose energizing the system with a selectively operable external system controller device for communicating remotely via telemetry with the shunt system. In Saul 495, the system is *connected* to a combined power

supply and controller. (Saul 495 page 5, lines 57-59). Saul 945 does not teach or even suggest that the system can be remotely energized via telemetry, as required by amended claim 1.

Accordingly, independent claim 1, as well as claims 2-16, which depend directly or indirectly therefrom, distinguish over Saul 495 and represent allowable subject matter.

Rejection Pursuant to 35 U.S.C. §103

The Examiner rejects claims 9 and 17-27 pursuant to 35 U.S.C. §103(a) as being obvious over Saul 495 in view of US 2003/0032915 A1 to Saul ("Saul 915"). The Examiner asserts that "Saul 495 discloses the apparatus substantially as claimed by applicant with the exception of a pressure sensor." The Examiner relies on Saul 915 to teach this feature, arguing that it would have been obvious to modify the device of Saul 495 in view of Saul 915 to arrive at the claimed invention. Applicant respectfully disagrees.

Claim 9 depends from independent claim 1 which, as described above, recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient. The method includes energizing the system with a selectively operable external system controller device for communicating remotely via telemetry with the shunt system. Similarly, independent claim 17, as amended, recites an apparatus for regulating cerebrospinal fluid flow including an implantable shunt system and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system.

As explained above, Saul 945 fails to teach or even suggest energizing the system with a selectively operable external system controller device for communicating remotely via telemetry with the shunt system. Saul 915 does not remedy the deficiencies of Saul 945 because Saul 915 also fails to disclose energizing the system with such a controller. Saul 915 discloses a method and apparatus for lowering elevated intracranial pressure utilizing a fluid drainage controller which regulates the drainage of CSF based on a cardiac or other transient component of the patient's intracranial pressure. In Saul 915, a programmed controller is used to open or close a valve in response to increases or decreases in the transient component of the patient's intracranial pressure. (Saul 915 page 4, lines 21-25.) The controller is contained *within* the system and is programmed to automatically open or close the valve as the transient component of intracranial pressure increases or decreases. Saul 915 fails to teach or even suggest an external system

controller device for communicating remotely via telemetry with the shunt system, as required by claims 1 and 17.

Moreover, there is no motivation to modify Saul 915 to include an external controller. The method and apparatus disclosed by Saul 915 require continuously monitoring a patient's intracranial pressure in order to maintain a target pressure in the ventricles over a period of time. In contrast, the method and apparatus of the claimed invention require the patient or attending physician to energize the system using the external controller device. No person having ordinary skill in the art would be motivated to modify a method and device aimed at continuous, automatic operation to include the intervening step of energizing.

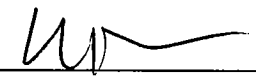
Accordingly, independent claims 1 and 17, as well as claims 2-16 and 18-27 which depend directly or indirectly therefrom, distinguish over Saul 495 and Saul 915, taken alone or combined, and represent allowable subject matter.

Conclusion

In view of the above amendments and remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

Date: May 16, 2006



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